

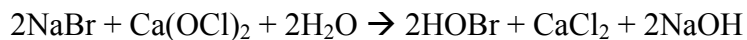
Attachment 3
Revised Environmental Assessment

- 1. Date** July 9, 2012
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4. Description of Proposed Action:

The action requested in this Notification is the establishment of a clearance to permit the use of hypobromous acid (CAS Reg. No. 13517-11-8), generated on-site from an aqueous mixture of sodium bromide (CAS Reg. No. 7647-15-6) and sodium, potassium, or calcium hypochlorite (CAS Reg. No. 7681-52-9, 7778-66-7, or 7778-54-3), as an antimicrobial agent in process water and ice for poultry products. The hypobromous acid is intended for use at a level not to exceed that needed to provide the equivalent of 450 ppm available bromine in water or ice used to process poultry products.

Hypobromous acid is made on-site by mixing sodium bromide and one of three oxidizers in the process water, as follows:



After undergoing chemical reduction during use in the process water, the hypobromous acid converts to bromide ion (Br⁻).

This product is for use in poultry processing plants that may be located throughout the United States. The expected route of disposal for wash water that has been treated with hypobromous acid is the processing plant wastewater treatment facility. Hypobromous acid is generated at the level described above in the front end of the wash water. Waste water ultimately runs into drains and enters the processing plant water treatment facility. This water is collected and treated by the facility prior to being sent to a publicly owned treatment works (POTW). Only minor quantities are lost to evaporation into the air.

5. Identification of Substances that are the subject of the Proposed Action:

a. Introduction of substances into the environment as a result of manufacture:

Under 21 C.F.R. § 25.40(a), an environmental assessment (EA) ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated substances. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of hypobromous acid. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances into the environment as a result of use/disposal:

Hypobromous acid will be used at a level not to exceed that needed to provide the equivalent of 450 ppm available bromine in water or ice used to process poultry products. After undergoing chemical reduction during use in the process water, hypobromous acid converts to bromide ion (Br⁻).

The hypobromous acid is highly reactive and is not expected to survive transit through the processing system given the high organic content of the process water and other aqueous waste streams. (The half-life of hypobromous acid in low-demand tap water has been estimated by EPA as 125 hours. The hypobromous acid will degrade far more rapidly in the aqueous systems present in the processing plant because of the high organic material content.) Thus, it is fully expected that no hypobromous acid will be released from the processing plant.

In addition, the oxidizers used to convert the sodium bromide into hypobromous acid create inert salts. Each mole of sodium bromide converted by the hypochlorite oxidizing source will yield a finite amount of salt relative to the chemical identity and corresponding reaction stoichiometry for each source. Based on the molecular weights and stoichiometry for each compound, the following amounts of salt for each source of hypochlorite will be created in the process and wastewater:

Sodium hypochlorite source

1 mol NaBr produces 1 mol of NaCl: $1 \text{ g NaBr} \times (58.4 \text{ g/mol NaCl} \div 103 \text{ g/mol NaBr}) = 0.57 \text{ g NaCl}$.

Potassium hypochlorite source

1 mol NaBr produces 1 mol of KCl: $1 \text{ g NaBr} \times (74.6 \text{ g/mol KCl} \div 103 \text{ g/mol NaBr}) = 0.72 \text{ g KCl}$.

Calcium hypochlorite source

1 mol NaBr produces 0.5 mol CaCl₂: $1 \text{ g NaBr} \times [0.5 \times (111 \text{ g/mol CaCl}_2 \div 103 \text{ g/mol NaBr})] = 0.54 \text{ g CaCl}_2$.

For these reasons, this EA focuses on the bromide ion and the chloride salts as the principal byproducts that may be released as a result of the proposed use of the FCS. We also

consider the environmental fate of bromoform, as it may be present as a result of the use of the antimicrobial solution. Introduction of hypobromous acid, bromoform, and the chloride salts into the environment will take place primarily via release in wastewater treatment systems. The total amount of hypobromous acid used at a typical facility can be estimated as shown below, although the actual amounts used will vary, depending on the available bromine concentration needed to treat the organic load in the process water and the amount of the food processed.

As a conservatism, and for the sake of simplicity, we have simply assumed that the level of bromide ion present for each application is equivalent to the starting level of “available bromine.”¹ Thus, we have used worst-case levels of 450 ppm bromide for poultry products.

c. Wastewater Treatment of Discharged Process Water

i. Poultry Processing

In poultry processing facilities, the defeathered, eviscerated carcasses are generally sprayed before being chilled via submersion in baths. The carcass is carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Chiller baths typically include a “main chiller” bath, as well as a “finishing chiller” bath, both containing the FCS. Parts and organs may also be chilled by submersion in baths containing the antimicrobial agent. Again, the majority of the solution containing the antimicrobial agent drains from the poultry carcasses and enters the plant’s wastewater processing treatment facilities.

The poultry industry added “finishing chillers” in response to the U.S. Department of Agriculture Food Safety and Inspection Service’s (FSIS) new performance standards for *Campylobacter* and *Salmonella*. The finishing chiller combines a high-dose (e.g., 450 ppm) treatment with shorter dip times to treat *Campylobacter*, as required by its dose-response characteristics. In contrast, the main chiller targets primarily *Salmonella*, which is a time-responsive bacteria that requires a longer residence time in the chiller bath, but does not require the high antimicrobial concentration. We understand that typical industry practice is to have the high-concentration finishing chiller solution feeding the main chiller.² Since poultry are in the finishing chiller for only a very short residence time, it is not economically or environmentally feasible to drain the water from the finishing chiller baths into the wastewater treatment facilities.³ Instead, as permitted by 9 CFR 416.2(g)(3), the finishing chiller water is recycled into the main chiller system.

¹ Based on stoichiometric considerations, the level of bromide ion present will be less than the stated level of “available bromine.” If one assumes that available bromine is equivalent to Br₂, bromide ion would be 50% of the available bromine level. If one assumes that available bromine is attributed solely to HOBr, bromide ion would be 82% of the “available bromine” value.

² A typical main chiller/finishing chiller schematic is provided in Attachment 2 to the Environmental Assessment for FCN 1098, and is included here as Appendix A.

³ See Environmental Assessment of FCN 1098, page 102, for approximate poultry residence times in finishing and main chiller baths, which are estimated to be 40-120 minutes in the main chiller, and 15-30 seconds in the finishing chiller. This EA is available at <http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM291252.pdf>, and is included as Appendix B.

The finishing chiller bath will typically contain the maximum concentration of the FCS, 450 ppm, but contains a much lower volume of water. The contents of the finishing chiller feed the main chiller as a water source. Since much greater amounts of water are present in the main chiller (roughly 10 times that of the finishing chiller), the FCS is significantly diluted in the main chiller. With respect to environmental impact, it is the contents of the main chiller that pass into the wastewater treatment system and are ultimately released to the environment. While the FCS is expected to be diluted significantly in the main chiller, we have conservatively assumed that the concentration of the FCS in the main chiller can be as high as 450 ppm.⁴ While this is highly unlikely from an economic standpoint, as significant amounts of the FCS would need to be added to the main chiller to maintain a concentration of 450 ppm in such a large volume of water, we have used 450 ppm as a worst-case.

For the purposes of our assessment, we will assume that a typical (medium) poultry facility process 200,000 birds per day.⁵ We will also assume that a combined 25,000 gallons of water is initially added to the main chiller/finishing chiller baths, and that 0.5 gal./carcass is added as a supplement for “make up” water. The total water volume based on immersion, assuming that the FCS is present in both water sources, is calculated as follows:

Chiller bath initial water volume = 25,000 gallons

Chiller bath make up water = 0.5 gal./carcass x 200,000 carcasses/day = 100,000 gal./day

We understand that the water usage estimates provided in the Environmental Assessment for FCN 323 still represent typical usage scenarios, thus we will assume that spray applications use 0.25 gallons of water per carcass and that the spray water contains the FCS and its constituents.⁶

Spray volume = 0.25 gal./carcass x 200,000 carcasses/day = 50,000 gallons

Thus, the total water volume containing the FCS is equal to 175,000 gallons (25,000 + 100,000 + 50,000), or 662,000 kg.

For poultry applications, spray and immersion bath solutions of 450 ppm of available bromine are used. Again, as a conservatism, we have simply assumed that this level of available bromine is equivalent to 450 ppm of bromide ion.

Thus, the amount of bromide ion, the chloride salts, and bromoform present in the rinse water is calculated as follows.

Bromide ion = 450 mg/kg x 662,000 kg x 1 kg/10⁶ mg = 300.0 kg bromide ion.

⁴ The concentration of the FCS in the main chiller was estimated by the Notifier of FCN 1098 to be approximately 40-100 ppm following dilution of the 450 ppm available bromine solution added to the finishing chiller. See Environmental Assessment for FCN 1098, page 101.

⁵ See Northcutt, J.K. and Jones, D.R.; A Survey of Water Use and Common Industry Practices in Commercial Broiler Processing Facilities, Poultry Science Association, Inc., USDA-ARS, 2004.

⁶ See Environmental Assessment of FCN 323, Section 6.b., page 239, included as Appendix C.

Further, based on the mol ratios calculated previously, the following quantities of salts would be produced:

$$\text{NaCl: } 300.0 \text{ kg bromide} \times 0.57 \text{ g-NaCl/g-bromide} = 171.0 \text{ kg NaCl}$$

$$\text{KCl: } 300.0 \text{ kg bromide} \times 0.72 \text{ g-KCl/g-bromide} = 216.0 \text{ kg KCl}$$

$$\text{CaCl}_2: 300.0 \text{ kg bromide} \times 0.54 \text{ g-CaCl}_2\text{/g-bromide} = 162.0 \text{ kg CaCl}_2$$

For bromoform, we have used data generated for poultry in FCN 334 to determine worst-case levels of bromoform in the rinsate. Specifically, based on data contained in FCN 334,⁷ it was determined that 45.3 ppb bromoform was present in the rinsate based on an available bromine level of 78 ppm. Conservatively assuming a proportional increase in bromoform levels, we calculate a maximum of 261 ppb bromoform based on 450 ppm available bromine.⁸ Thus, assuming that bromoform is present in the water containing the FCS at a concentration of 261 ppb, we calculate bromoform as follows:

$$662,000 \text{ kg/day} \times 261 \text{ } \mu\text{g/kg} \times 1 \text{ kg}/10^9 \text{ } \mu\text{g} = 0.173 \text{ kg bromoform per day.}$$

To calculate the concentration at which these substances may be present in the poultry facility plant wastewater system, we need to know the total volume of waste water produced, which includes any water used in the facility (e.g., rinsing water, handwash stations, plant sanitation, etc.). According to a survey conducted by USDA, for medium-sized facilities processing 125,000-250,000 birds per day, an average water rate of 26 L/bird is used (equivalent to 7 gallons/bird).⁹

$$7 \text{ gal./bird} \times 200,000 \text{ birds/day} = 1,400,000 \text{ gallons of waste water per day.}$$

$$1,400,000 \text{ gal./} \times 3.785 \text{ L/gal} = 5,300,000 \text{ L/day} = 5,300,000 \text{ kg/day}$$

To this value, we also factor in dilution by a POTW with a typical daily flow of 25 million gallons per day (94,600,000 kg). Thus, the total water diluent per day is approximately 100,000,000 kg per day (5,300,000 + 94,600,000 = 99,900,000).

The concentration of each component of the FCS is then calculated as such:

Bromide ion

$$300.0 \text{ kg bromide/day} \div 100,000,000 \text{ kg water/day} = 3 \times 10^{-6} \text{ kg bromide/kg water} = 3 \text{ ppm.}$$

⁷ Included here as Appendix D.

⁸ $45.3 \text{ ppb} \times 450/78 = 261 \text{ ppb.}$

⁹ See Northcutt, J.K. and Jones, D.R.; A Survey of Water Use and Common Industry Practices in Commercial Broiler Processing Facilities, Poultry Science Association, Inc., USDA-ARS, 2004. Also, see Wesley et al, *Poultry Sci.* 64:476 (1985).

Chloride salts

$171.0 \text{ kg NaCl/day} \div 100,000,000 \text{ kg water/day} = 1.7 \times 10^{-6} \text{ kg NaCl/kg water} = 1.7 \text{ ppm.}$

$216.0 \text{ kg KCl/day} \div 100,000,000 \text{ kg water/day} = 2.2 \times 10^{-6} \text{ kg KCl/kg water} = 2.2 \text{ ppm.}$

$162.0 \text{ kg CaCl}_2\text{/day} \div 100,000,000 \text{ kg water/day} = 1.6 \times 10^{-6} \text{ kg CaCl}_2\text{/kg water} = 1.6 \text{ ppm.}$

Bromoform

$0.173 \text{ kg CH}_3\text{Br/day} \div 100,000,000 \text{ kg water/day} = 1.7 \times 10^{-9} \text{ kg/kg water} = 1.7 \text{ ppb.}$

For purposes of the EA, it is assumed that all of the product that is used on the carcasses will ultimately enter the facility's wastewater treatment processing plant.

To summarize, the worst-case release of wastewater to the environment as a result of this intended use of hypobromous acid may contain a total bromide ion concentration of 3 ppm, a sodium chloride concentration of 1.7 ppm, a potassium chloride concentration of 2.2 ppm, a calcium chloride concentration of 1.6 ppm, and a bromoform concentration of 1.7 ppb.

It is important to recall at this point that we assumed the starting bromide levels were equivalent to the amount of available bromine for each application. Since available bromine is expressed as Br_2 , bromide ion is actually present at 50% of the starting available bromine levels, since bromide ion (Br^-) weighs half as much as bromine (Br_2). As a conservatism, we have not reduced our bromide ion calculations by 50%.

We note that releases to surface water from a POTW or onsite treatment system would be subject to the terms and conditions of a National Pollution Discharge Elimination System (NPDES) permit.

7. Fate of Emitted Components in the Environment:

According to the calculations detailed above, bromide ion, sodium chloride, potassium chloride, calcium chloride, and bromoform may be present in waste water received by POTWs at concentrations up to 3 ppm, 1.7 ppm, 2.2 ppm, 1.6 ppm, and 1.7 ppb, respectively. These also represent the maximum concentrations in effluent exiting POTWs assuming, very conservatively, that none of the bromide ion, chloride salts, or bromoform is lost during processing at the POTW. The actual concentrations at which the byproducts may be present in receiving waters into which POTW effluent is discharged will be even lower due to the dilution effect of mixing effluent with the water flowing through the receiving river or other body. Assuming that the effluent concentrations are diluted by as little as 10-fold, the maximum concentrations of bromide ion, sodium chloride, potassium chloride, calcium chloride, and bromoform in the receiving water will be 0.3 ppm, 0.17 ppm, 0.22 ppm, 0.16 ppm, and 0.17 ppb respectively.

The bromide ion may remain in the treated waste water released from the POTW unless special steps are taken to remove it from the POTW effluent. As demonstrated by the data

discussed in Item 8 below, however, it is unlikely that a receiving POTW would need to put such special steps into place given the absence of any environmental concern regarding the possible aqueous release of bromide ion at the maximum level calculated.

In the presence of water, bromoform is slowly broken down at the water surface where oxygen is available, but is degraded much quicker in deep water and in water that is underground where there is a lot less oxygen. Nevertheless, any bromoform that is present as a result of the intended use (0.17 ppb) is much lower than the levels of bromoform found in drinking water, which range from 1-10 ppb. It should also be noted that these drinking water levels do not have related adverse health effects.¹⁰ Bromoform is soluble in water or will evaporate into the air as a gas. Despite being relatively stable in the air, bromoform will slowly react with other chemicals in the air and break down, at a rate of about 50% in 1 or 2 months. Therefore, because bromoform is present at such low levels in the water to begin with, the levels at which bromoform could potentially be present in the air are not considered to be of environmental concern.

8. Environmental Effects of Released Substances:

Bromide ion is of low toxicity to aquatic organisms. Attached to this EA, as Appendix E is a printout of the results of a search of an EPA ecotoxicity database for the compound sodium bromide.¹¹ (A search of the same database for “bromide ion,” CAS Reg. No. 24959-67-9, did not yield any hits.) Since sodium bromide dissociates in water to yield the free sodium and bromide ions, the data on sodium bromide serve to provide useful information on the toxicity of the bromide ion, itself.

As indicated by the printout in Appendix E, a large amount of data is available on the toxicity of sodium bromide to both fresh water and salt water organisms. The data include both LC₅₀ values obtained from acute toxicity testing, as well as no-observed effect concentrations (NOECs) for a variety of toxicity endpoints from long-term exposures. Here, we rely on LC₅₀ values.

It should be noted from the outset that, although the search term used was “sodium bromide,” the data retrieved from the database include the results of certain studies that actually were designed to investigate the toxicity of hypobromous acid generated by activated sodium bromide. In particular, these studies include three acute toxicity assays conducted by an industry task force to support a pesticide re-registration effort for sodium bromide used in the generation of hypobromous acid.¹² The studies in question report a 96-hour LC₅₀ of 0.18 ppm for opossum

¹⁰ See Toxicological Profile for Bromoform and Dibromochloromethane, available at <http://www.atsdr.cdc.gov/ToxProfiles/tp130.pdf>

¹¹ Specifically, the database searched was the Environmental Protection Agency’s ECOTOX Ecotoxicology Database, located at <http://www.epa.gov/ecotox/>.

¹² Surprenant, D. (1988) *Acute Toxicity of Hypobromous acid to Mysid Shrimp (Mysidopsis bahia) Under Flow-through Conditions*: SLS Report. No. 88-5-2722; Study No. 1199.0188.6109.515; Surprenant, D. (1988) *Acute Toxicity of Hypobromous acid to Eastern Oysters (Crassostrea virginica) Under Flow-through Conditions*: SLS Report. No. 88-5-2726; Study No. 1199.0188.6109.504; Surprenant, D. (1988) *Acute Toxicity of Hypobromous acid*

shrimp, a 96-hour LC₅₀ of 0.47 ppm for the Virginia oyster, and a 96-hour LC₅₀ of 0.19 ppm for Sheepshead Minnow. The reference given in the ECOTOX database (see Reference Number 344) for all three studies is to an EPA Pesticide Ecotoxicity Database in the Environmental Fate and Effects Division of the Office of Pesticide Programs. The studies in question are not currently in the public domain. However, the Notifier, Albemarle Corporation, was a participant in the task force that carried out the studies and confirms that the actual test compound in the noted studies was hypobromous acid, as suggested by the titles of the studies provided in the footnote above. Specifically, the studies were conducted by combining sodium bromide with sodium hypochlorite in a mole ratio of 1.2 to 1.0 to yield hypobromous acid. Thus, the data obtained in these studies are not directly relevant to the current EA as hypobromous acid is not expected to be released as a result of the proposed use of hypobromous acid.

Additional data included in the printout are from a 1999 paper by Fisher, et al. (reference number 6320 in the ECOTOX database)¹³ in which sodium bromide again was tested in the presence of an activator (sodium hypochlorite) designed to generate hypobromous acid. Thus, this testing also was intended to examine the toxicity of bromine oxidants, not bromide ion, *per se*.¹⁴ Therefore, the various toxicity data points ascribed to the Fisher paper also are of no direct relevance to the present evaluation of the aquatic toxicity of bromide ion.

Once these data are excluded from consideration, it is evident from Appendix E that bromide ion is not acutely toxic to freshwater or marine organisms. A sampling of the relevant data is provided in the following table. Note that, where more than one value is given for the same endpoint in the same species, we have included only the lowest relevant value.

Test Organism	Endpoint	Duration	Concentration
Daphnia magna	LC ₅₀	24 hours	500 mg/L
Bluegill	LC ₅₀	96 hours	> 1000 ppm
Rainbow trout	LC ₅₀	96 hours	>1000 ppm
Medaka, high eyes	LC ₅₀	34 days	1500 mg/L
Medaka, high eyes	LC ₅₀	72 hours	24,000 mg/L
Fathead minnow	LC ₅₀	96 hours	16479 mg/L
Guppy	LC ₅₀	124 days	7800 mg/L
Guppy	LC ₅₀	96 hours	16,000 mg/L

The lowest LC₅₀ given in the table above is 500 mg/L, in *Daphnia magna*. Other LC₅₀ values cited in the database for sodium bromide in *Daphnia* range from 6100 mg/L to over 15,000 mg/L. Thus, relying on the lowest LC₅₀ value of 500 mg/L clearly represents a conservative estimate of the toxicity of bromide ion to this species.

to Sheepshead minnow (*Cyprinodon variegatus*) Under Flow-through Conditions: SLS Report. No. 88-5-2736; Study No. 1199.0188.6109.505. Unpublished studies prepared by Springborn Life Sciences, Inc.

¹³ This paper was included as Appendix B to FCN 1122, and is included here as Appendix F..

¹⁴ As noted on page 766 of the paper, although excess sodium bromide was used in this testing, the toxicity observed was considered by the authors to be due to the oxidants and not to the sodium bromide.

Based on the entirety of the data available, we respectfully submit that the use of a LC₅₀ value of 500 mg/L is sufficiently conservative for purposes of establishing a safe level of bromide ion in bodies of water receiving POTW effluent.

The maximum concentration at which bromide ion may be present in rivers or other bodies of water that receive POTW effluent was estimated above as 0.3 ppm (0.3 mg/L). This is more than 1500 times lower than the lowest LC₅₀ value.

To further put into perspective the possible release levels of bromide ion as a result of the proposed use of hypobromous acid, we note that a survey of bromide levels in drinking water supplies indicates that bromide is commonly present at far higher levels than those calculated here. Specifically, a survey report prepared by Amy, G., et al, "Survey of Bromide in Drinking Water and Impacts on DBP Formation" demonstrates average Br⁽⁻⁾ ion concentrations in randomly selected utility samples of 61 to 64 mg/L (ppm).¹⁵ The worst-case release concentration calculated here represents a minute fraction of this background level.

As stated previously, the active microbial agent HOBr (hypobromous acid) will not be released from the processing facilities, because HOBr undergoes reduction to bromide ion during use. However, EPA has assessed ecological effects in a risk assessment for hypobromous acid from activated sodium bromide used in once-through cooling systems in freshwater and estuarine environments. The summary from the Inorganic Halide Re-registration Eligibility Decision (RED) Facts, is pertinent:

"As discussed earlier, EPA conducted a Tier IC EEC screening model for hypobromous acid to estimate the maximum concentration that occurs immediately downstream from an industrial point source discharge site. The results for the high exposure case are comparable to the amounts detected in the two Potomac River aquatic residue studies, one of which showed high concentrations of hypobromous acid as far downstream as 80 meters. Based on these studies, the Agency presumes risk to freshwater and estuarine fish and invertebrates at the point of discharge and downstream to 80 meters.

However, the modeling results for "typical" sites are well below the levels of concern for fish and invertebrates. These results indicate that (activated) sodium bromide can be used at typical sites without impact most of the time. Since the discharge of hypobromous acid is limited by the NPDES permit program administered by EPA's Office of Water, the Agency will be able to control the discharge of hypobromous acid on a site-by-site basis so that toxic levels are avoided. Based on this modeling, EPA also presumes a risk to endangered freshwater and estuarine/marine

¹⁵

This report was included as Attachment D to FCN 1122, and is included as Appendix G to this EA.

organisms in “worst case” situations. However, “typical” discharge levels are below those of concern for endangered species.”¹⁶

With regard to the environmental fate of bromoform, according to EPA’s Clean-Up Information (CLU-IN) program, there is limited data on the ecotoxicity of bromoform. However, the PAN Pesticides Database includes data on aquatic organisms. These organisms include crustaceans, fish, and zooplankton, and bromoform is reported as “slightly toxic” to all three types of organisms.¹⁷ The lowest average LC₅₀ value for bromoform was in Sheepshead Minnow and is reported as 7,100 µg/L (ppb) and given the designation of “moderately toxic.”¹⁸ The worst case value calculated here, 0.17 ppb, is orders of magnitude lower than the lowest reported LC₅₀ value, and therefore we respectfully submit that the addition of bromoform into the environment will not pose a safety concern.

The chloride salts (NaCl, KCl, CaCl₂) are ubiquitous in nature and do not pose a health or safety concern at the calculated levels. Taking sodium chloride as an example, sodium is an essential element naturally present in drinking water at levels ranging from 0-500 ppm. The National Research Council recommends no more than 2400 mg of sodium per day.¹⁹ If we assume that sodium is present in water at 50 mg/L (50 ppm), and that an individual consumes 2 liters of water per day (*i.e.*, eight 8-oz glasses), an individual consumes 100 mg/day sodium from drinking water, or 12.5 mg/glass of water. This would be considered a “very low sodium” food per FDA. Further, the level of sodium chloride calculated for this application was at most 1.7 ppm, well below typical sodium chloride levels used in the example above. The same can be said for the potassium and calcium salts.

9. Use of Resources and Energy

The use of hypobromous acid will not require additional energy resources for treatment and disposal of waste water. The raw materials used in the production of the compound are commercially manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the proposed use of hypobromous acid is not significant. Moreover, as hypobromous acid will be used in place of other antimicrobial treatments that currently are permitted for use in process water for poultry products the use of hypobromous acid as described will not lead to a net increase in the consumption of resources and energy.

¹⁶ R.E.D. Facts Inorganic Halides, EPA-738-F-93-015, available at <http://www.epa.gov/oppsrrd1/REDs/factsheets/4051fact.pdf>.

¹⁷ Available at: http://www.clu-in.org/contaminantfocus/default.focus/sec/Dense_Nonaqueous_Phase_Liquids_%28DNAPLs%29/cat/Toxicology/p/2/n/1

¹⁸ It should be noted that, of all of the organisms present, the Sheepshead Minnow is the only organism to receive the designation of “moderately toxic.” Full table of data is available at: http://www.pesticideinfo.org/List_AquireAll.jsp?Rec_Id=PC42788

¹⁹ <http://water.epa.gov/scitech/drinkingwater/dws/ccl/sodium.cfm#four>

10. Mitigation Measures

Based on the foregoing, no significant adverse environmental impacts are expected to result from the intended use of hypobromous acid. Thus, the proposed use of the subject food-contact substance is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of other products by the poultry processing industries; such action would have no environmental impact. In view of the excellent properties of hypobromous acid as an antimicrobial treatment for these uses, the improvements in food safety that will result from its use, and the absence of any identified significant environmental impact that would result from its use, the clearance of the use of hypobromous acid as described herein appears to be environmentally safe and desirable in every respect.

12. List of Preparers

Jason P. Schmidt, Ph.D., Scientist, Keller and Heckman LLP

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: July 9, 2012

Devon Wm. Hill



Keller and Heckman LLP
Counsel for Albemarle